Section 5- 510(k) Summary

Submitter :	St Jude Medical, CRMD 15900 Valley View Court Sylmar, CA 91324 Establishment Registration Number: 2017865
Contact Person :	Colleen Canan Staff Regulatory Affairs Specialist Phone (818) 493 2960 Fax (818) 493 3615
Date Prepared :	January 27, 2012
Trade Name :	CPS Direct™ MediGuide™ Enabled Outer Guide Catheter and accessories
Classification :	Class II – 21 CFR 870.1250 Catheter Percutaneous
Product Code :	DQY
Predicate Device:	The subject device is equivalent to the following St Jude Medical and MediGuide Devices St Jude Medical CPS Direct™ SL II Slittable Outer Catheter (K092075 cleared on August 7, 2009) MediGuide Guided Measurement Catheter (GMC) (K091781 cleared on October 16, 2009)
Device Description :	The St. Jude Medical CPS Direct MediGuide Enabled slittable outer guide catheter is made from PEBAX and reinforced with a stainless steel braid. The shaft has progressively decreasing durometers of PEBAX from the proximal to the distal end with a soft, atraumatic distal tip. The distal end is embedded with a sensor coil to enable device tip projection onto the MediGuide system and tungsten stripes for fluoroscopic visibility. The hub contains an integrated hemostasis valve and the proximal shaft is integrated into the hub creating a slit channel. The hub contains a sideport with extension tubing for contrast delivery, aspiration or saline flush using a 3-way stopcock. In addition, the hub contains a port for the connector cable.

Intended Use:	The St Jude Medical CPS Direct MediGuide Enabled slittable outer guide catheter is designed for intracardiac access of the venous system of the heart and to serve as a conduit during implantation for the delivery of contrast medium and St. Jude Medical devices (including implantable left heart leads and delivery tools), and support of fluids where minimizing blood loss is essential. The CPS Direct MediGuide Enabled slittable outer guide catheter is used with the MediGuide System to enable real-time tip positioning and navigation. The MediGuide system is indicated for use as an adjunct to fluoroscopy. In addition, the CPS Direct MediGuide Enabled slittable outer guide catheters can work with inner catheters as a system
Comparison to Predicate Devices	The St Jude Medical CPS Direct MediGuide Enabled slittable outer guide catheter (from herein referenced as CPS Direct MediGuide Enabled outer catheter kit) has a similar intended use and the same fundamental scientific technology as the predicate devices. All technological characteristics of CPS Direct MediGuide Enabled outer catheter kit are substantially equivalent to the predicate devices including packaging, biocompatibility, sterilization, and labeling. Where differences exist between the subject device and the predicate devices performance testing demonstrated that these differences do not adversely affect the safety and effectiveness of the subject device.
Conclusion :	St Jude Medical considers the CPS Direct MediGuide Enabled outer catheter kit to be equivalent to the predicate devices listed above. This conclusion is based upon the device similarities in design, technological characteristics, principle of operation, materials and indications for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

St. Jude Medical
c/o Ms. Colleen Canan
15900 Valley View Court
Sylmar, CA 91342

MAY 11 2012

Re: K120296
Trade/Device Name: CPS Direct MediGuide Enabled Outer Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous catheter
Regulatory Class: Class II (two)
Product Code: DQY
Dated: May 7, 2012
Received: May 9, 2012

Dear Ms. Canan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use

Device Name: CPS Direct™ Mediguide Enabled™ Slittable Outer Guide Catheter
Models DS2M021, DS2M022, DS2M023

Indications for Use: The St. Jude Medical™ CPS Direct™, Mediguide™ Enabled slittable outer guide catheter is designed for intracardiac access of the venous system of the heart and to serve as a conduit during implantation for the delivery of contrast medium and St. Jude Medical™ devices (including implantable left heart leads and delivery tools), and support of fluids where minimizing blood loss is essential. The CPS Direct™, Mediguide Enabled slittable outer guide catheter are used with the Mediguide™ System to enable real-time tip positioning and navigation. The Mediguide™ system is indicated for use as an adjunct to fluoroscopy. In addition, the CPS Direct™, Mediguide™ Enabled slittable outer guide catheters can work with inner catheters as a system.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K120296